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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,634	11/12/2003	Gary T. Neel	02-1134-d	7985
22852	7590	06/23/2005	EXAMINER	
FINNNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			MALLARI, PATRICIA C	
		ART UNIT	PAPER NUMBER	
		3736		

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/706,634	NEEL ET AL.
	Examiner Patricia C. Mallari	Art Unit 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 April 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 25-43 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 25-32 is/are allowed.
- 6) Claim(s) 33,35-39 and 41-43 is/are rejected.
- 7) Claim(s) 34 and 40 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12 November 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/30/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

This is a non-final Office action. New grounds of rejection have been presented which were not necessitated by the applicants' amendment to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,728,074 to Castellano in view of US Patent No. 5,837,546 to Allen et al. and US Patent No. 6,591,125 to Buse et al.

Castellano teaches a method of using a test strip to test a blood sample comprising, wherein the user inserts the test strip 204 into a meter 202, the meter 202 being in sleep mode (col. 14, lines 37-40; col. 20, line 65-col. 21, line 5) and responsively entering an active mode. The test strip includes a sample chamber, and a blood sample is applied the sample chamber of the test strip 204 (col. 14, lines 52-56). The meter 202 detects the blood sample in the chamber (col. 14, lines 56-57; col. 15, lines 9-12) and makes a measurement determining a test result (blood glucose) based on a current measurement (col. 14, lines 47-49). Castellano is silent as to the details of the meter entering the active mode from the sleep mode and detecting the blood sample in the chamber and the current measurement.

Buse teaches a test strip having a working electrode 502, 522 and counter electrodes 510,512 or 530, 532, 534 (figs. 18A-C, 19A-C; col. 31, lines 44-57; col. 34,

lines 1-9). The test strip includes working electrode 502, counter electrode 510, and fill-detect electrodes 502, 512. During operation, the meter applies a voltage between fill electrodes 502, 512 and measures a fill-detect current flowing between the fill-detect electrodes 502, 512 (col. 51, lines 38-50). Once the meter has determined that the sample chamber has been filled, the meter begins reading the analyte concentration in the sample by applying an assay voltage between the working electrode 502 and a counter electrode 510 (col. 52, lines 53-63) and measures a resulting current to derive an analyte concentration (col. 38, lines 29-35; col. 38, line 54-col. 39, line 33; col. 39, lines 59-67 of Buse). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the means and method described by Buse for detecting the blood sample in the chamber and for detecting a current measurement as that of Castellano, since Castellano teaches a meter capable of detecting the presence of a sample in a sample chamber of a test strip and capable of determining an glucose concentration based on a current measurement, and Buse describes a means for doing so. Castellano, in view of Buse is silent as to the details of the meter entering the active mode from the sleep mode.

Davies teaches a test strip including an auto-on conductor 10 (fig. 2 of Davies). The test strip is inserted into a meter, the meter being in a sleep mode. The auto-on conductor 10 completes a circuit, causing the meter to detect an auto-on current through the auto-on conductor 10 and responsively enters an active mode. Therefore, it would have been obvious to one of ordinary skill in the art to use the means and method of Davies as that of Castellano, as modified by Buse, since Castellano, as modified,

discloses the meter entering an active mode in response to the insertion of the test strip, and Davies teaches an appropriate means and method of doing so.

Castellano, as modified by Buse and Davies teaches a test strip having a working electrode and two counter electrodes, wherein a working electrode and one of the counter electrodes are used as the pair of fill-detect electrode, rather than providing a separate pair of fill-detect electrodes. However, the applicants have not disclosed that providing the fill-detect electrodes separately from the working and counter electrodes solves any stated problem or is for any particular purpose. Moreover, it appears that the method would perform equally well with the test strip having a shared electrode used both for detecting a blood sample and for measuring a current indicative of a test result. Accordingly, the use of separate electrodes is deemed to be a design consideration that fails to patentably distinguish over the prior art of Castellano, as modified by Buse and Davies

Regarding claim 35, if the fill-detect current reaches a fill-detect threshold value within a predetermined time period, the meter provides a user-discernibly indication (col. 15, lines 9-12 of Castellano; col. 51, lines 38-50, col. 52, lines 53-56 of Buse et al.)

Regarding claim 36, the meter may further detect the blood sample in the sample chamber by applying a drop-detect voltage between the working and counter electrodes and measuring a drop-detect current between the electrodes (figs. 19A-C, 20A-C; col. 52, lines 9-16 of Buse et al.)

Regarding claim 41, the auto-on conductor 10 is electrically isolated from the electrodes (fig. 2; col. 4, lines 51-65 of Davies).

Regarding claim 42, the test strip comprises a base layer, and the electrodes and auto-on conductor comprise electrically conducting material disposed on the base layer (figs. 18A-C, 20A-C; col. 31, lines 43-61; col. 34, lines 1-16 of Buse; figs. 2 and col. 4, lines 45-65 of Davies).

Regarding claim 43, the auto-on conductor 10 is disposed on the test strip prior to the sample being applied (col. 4, lines 51-65; col. 5, lines 30-41 of Davies et al.)

Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castellano in view of Buse et al. and Davies et al., as applied to claims 33, 35, and 36 above. Castellano, as modified, fails to teach the meter starting an incubation time period. However, Buse teaches that the sample may be incubated for a period of time (col. 52, line 65-col. 53, line 16 of Buse et al.). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to incubate the sample for a time period in order to increase the rate of diffusion, oxidation or reduction of an analyte (col. 52, lines 66-67 of Buse et al.)

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Castellano, in view of Buse and Davies, as applied to claims 33, 35, and 36 above, and further in view of US Patent No. 5,438,271 to White et al. Castellano, as modified, lacks the meter validating the working and counter electrodes. However, White et al. teaches a method of measuring glucose in a blood sample wherein the meter validates the working 14 and counter 12 electrodes by applying a first validation voltage between the working and counter electrodes (col. 3, lines 39-54 and lines 60-67; col. 4, lines 24-35; fig. 3 of White). Therefore, it would have been obvious to one of ordinary skill in the art

at the time of invention to modify the method of Castellano, in view of Buse and Davies, with the method of White, in order to determine whether a sample strip has been inserted properly or improperly, thereby ensuring more accurate results.

Response to Arguments

Applicant's arguments, see pp.8-11, filed 4/15/05, with respect to the rejection(s) of claim(s) 33-38 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Castellano, as modified by Buse and Davies.

Allowable Subject Matter

Claims 34 and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 25-32 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

With regard to claim 34, the prior art of record fails to teach or fairly suggest a method of using a test strip to test a blood sample, said test strip including an auto-on conductor, wherein the auto-on current through the auto-on conductor develops an auto-on voltage drop across the auto-on conductor and the meter measures the auto-on voltage drop, in combination with all the other limitations of the claim.

With regard to claims 25-32 and 40, the prior art of record fails to teach or fairly suggest a method of measuring glucose in a blood sample wherein a meter validates the fill-detect electrodes on a test strip by applying a second validation voltage between the fill-detect electrodes while a first validation voltage is applied between the working and counter electrodes on the test strip in order to validate the working and counter electrodes. US Patent No. 5,438271 to White et al. teaches a method of measuring glucose in a blood sample wherein the meter validates the working 14 and counter 12 electrodes by applying a first validation voltage between the working and counter electrodes (col. 3, lines 39-54 and lines 60-67; col. 4, lines 24-35; fig. 3 of White). However, the reference fails to teach applying a second validation voltage between fill-detect electrodes while the first validation voltage is applied between the working and counter electrodes.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US Patent No. 5,320,732 to Nankai et al. also teaches a sensor strip and method of using wherein insertion of the sensor strip activates the meter but fails to disclose the meter detecting an auto-on current through an auto-on conductor of the sensor strip.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

pm
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